



Exhibit 1

12-1-11

12/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent of:	§	
	§	
Patentee: Dietlin, Francois et al.	§	Serial No.: 10/332,060
	§	
U.S. Patent No.: 6,992,218	§	Date Filed: August 4, 2003
	§	
Title: METHOD FOR OBTAINING	§	Date Issued: January 31, 2006
AQUEOUS FORMULATIONS	§	
OF OXIDATION-SENSITIVE	§	
ACTIVE PRINCIPLES	§	

URGENT PETITION TO DIRECTOR UNDER RULE 182 OR 181(a)(3) TO VACATE THE ORDER GRANTING THE PETITION TO REVIVE ABANDONED PATENT APPLICATION NO. 10/332,060 ABANDONED DUE TO NONCOMPLIANCE WITH 35 U.S.C. § 371

MS Petition
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

12/02/2011 EFLORES 00000002 6992218
 01 FC:1462

400.00 OP

Sir:

Exela Pharma Sciences, LLC; Exela PharmSci, Inc. and Exela Holdings, Inc. (collectively "Exela") file this urgent Petition, requesting that the US Patent & Trademark Office ("PTO") reconsider and withdraw its petition decision reviving abandoned U.S. patent application no. 10/332,060, which ultimately issued as U.S. Patent No. 6,992,218 ("the '218 patent"). Exela's Petition is specifically filed pursuant to 37 CFR § 1.182 seeking a ruling by the Director on an issue not otherwise provided for in the regulations. In the alternative, Exela's Petition is filed under 37 CFR § 1.181(a)(3) as one concerning an issue to be determined by the Director. To the extent the PTO believes any rules prevent consideration of Exela's Petition, Exela further petitions the Director

to suspend such rules under the power granted to the Director by 37 CFR § 183. As required, the petition fee of \$400 under 37 CFR 1.17(f) is provided herewith via form PTO/SB/17p and form PTO-2038. The Commissioner is authorized to charge any deficiency of fees.

Regarding the substance of Exela's Petition, as detailed in *ATA PTY LTD v. Int'l Game Tech.*, 491 F. Supp. 2d 916 (N.D. Cal. 2007),¹ the PTO's actions in reviving the subject patent application were clearly improper, outside of its statutory jurisdiction, and as explained herein, unconstitutional. Specifically, reviving the subject application under the lesser stringent "unintentional" standard violated the express language of 35 U.S.C. § 371(d), which mandates the more stringent "unavoidable" standard, and issuing a patent that removed information already in the public domain violated the constitutional mandate to promote the progress of science and useful arts. As such, the PTO should reconsider and withdraw its petition decision reviving application no. 10/332,060 that led to issuance of the '218 patent due to noncompliance with 35 U.S.C. § 371.

I. Summary of Argument

The PTO should reconsider and ultimately withdraw its decision reviving U.S. patent application no. 10/332,060 for at least two reasons. *First*, 35 U.S.C. § 371(d) expressly requires that any abandoned national stage patent application be revived only under the stringent "unavoidable" standard. The PTO's *ultra vires* decision to revive the subject application under the less-stringent "unintentional" standard was clearly contrary to this statutory mandate. Indeed, the PTO's inability to revive national stage applications under the "unintentional" standard is detailed in the well-

¹ *Reversed on other grounds by Aristocrat Techs. Australia PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008).

reasoned *Aristocrat* decision, rendered by the U.S. District Court for the Northern District of California.

Second, any laws passed by Congress and ultimately implemented by the PTO are limited by the constitutional mandate of promoting the progress of science and useful arts. In allowing for the revival of national stage applications, Congress has struck a balance between not removing information from the public domain and allowing applications that become abandoned, through no fault of the applicant, to be revived. By ignoring this balance struck by Congress and reviving the subject application under a lesser standard, the PTO has, in effect, removed information from the public domain in violation of Article I, Section 8, Clause 8 of the U.S. Constitution.

For either of these reasons standing alone, the PTO should reconsider and withdraw its decision reviving application no. 10/332,060, which ultimately issued as the '218 patent. The PTO's revival of the application that led to issuance of the '218 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law as set forth in § 706(2)(A) of the Administrative Procedure Act ("APA"), contrary to constitutional right, power, privilege, or immunity as set forth in § 706(2)(B) of the APA, in excess of statutory jurisdiction, authority, or limitations, or short of statutory right as set forth in § 706(2)(C) of the APA, and without observance of procedure required by law as set forth in § 706(2)(D) of the APA.

II. Factual History

A. Pending Hatch-Waxman Litigation Involving The '218 Patent

This petition stems from a pending patent infringement suit filed in the U.S. District Court for the District of Delaware under the Hatch-Waxman Act for infringement of, *inter alia*, the '218

patent. Petitioner, Exela, is a defendant in that pending litigation.² A copy of the complaint filed in the Delaware litigation is attached hereto as Exhibit A.

The Delaware litigation was brought by the assignee (SCR Pharmatop) and exclusive U.S. licensee (Cadence Pharmaceuticals, Inc.) of the '218 patent in response to Exela's filing of an Abbreviated New Drug Application (ANDA), seeking approval to make a generic version of a branded drug called Ofirmev®. Ofirmev basically is an injectable form of Tylenol. According to the Orange Book, Ofirmev® is allegedly protected by two U.S. patents, one of those patents being the '218 patent. The '218 patent expires on June 6, 2021 and currently is the latest expiring patent covering Ofirmev®.

But for the PTO's improper revival and issuance of the '218 patent, this patent would not be part of the pending litigation brought against Exela, and generic competition for Ofirmev® would commence no later than August 5, 2017 – the expiration date of the only other U.S. patent relating to Ofirmev®. The PTO's improper actions have detrimentally affected Exela and others seeking to make a generic version of Ofirmev®, and the consuming public who are forced to pay higher, brand prices for Ofirmev®.

B. Prosecution History of The '218 Patent

On June 6, 2000, SCR Pharmatop, the assignee of the entire interest of the US application no. 10/332,060, filed a French patent application FR 00 07231. One year later, on June 6, 2001, SCR Pharmatop filed in the US, under the Patent Cooperation Treaty ("PCT"), an international application ("PCT Application") no. PCT/ FR01/01749 claiming priority to the above-referenced French application. This application, filed as US application no. 10/332,060, ultimately issued in the

² Exela is a small pharmaceutical company, with a principal place of business in Lenoir, North Carolina, where Exela's R&D and manufacturing facilities are located. Exela has about 40 employees. Exela's primary business lies in the development of noninfringing drug formulations for branded drugs covered by unexpired patents. In its short existence, Exela has developed several noninfringing generic drug formulations. In many cases, the branded company has not filed suit under the Hatch-Waxman Act due the strength of Exela's noninfringement position.

United States on January 31, 2006 as the '218 Patent. The World Intellectual Property Organization published PCT/ FR01/01749 application on December 13, 2001 as WO01/93830.

During prosecution, the applicant, SCR Pharmatop, missed the deadline to pay the national fee, file the international application and required translation, submit the properly executed oath or declaration, and submit the amendments made to an originally filed foreign application as required under 35 U.S.C. § 371(c). As a result, the U.S. national stage application was abandoned under the express terms of 35 U.S.C. § 371(d).³ Once abandoned, any invention disclosed in the '218 patent passed into the public domain, and became free for anyone to exploit in the United States. *Penock v. Dialogue*, 27 U.S. 1, 16 (1829).

Nonetheless, on January 2, 2003, nearly a month after the statutory deadline had already lapsed and after any invention disclosed in the '218 patent had already passed into the public domain, SCR Pharmatop petitioned the PTO to revive its abandoned application stating that the delay was "unintentional." The PTO granted the petition on April 23, 2003, despite the clear and unambiguous statutory language requiring that any delay be "unavoidable," not merely "unintentional." See 35 U.S.C. § 371(d) ("Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was *unavoidable*." (emphasis added)).

Despite this clear statutory and constitutional error, the PTO subsequently forwarded the application to the National Stage Processing Branch of the PCT Operations for continued processing.⁴ U.S. application no. 10/332,060 eventually issued on January 31, 2006 as the '218

³ In fact, the applicant failed to comply with the requirements stated at 35 U.S.C. §§ 371(c)(1)(4). Each deficiency provides an independent basis for concluding that the U.S. national stage application was abandoned. 35 U.S.C. § 371(c)-(d).

⁴ The PTO also failed to follow 37 C.F.R. § 1.495(c) when it allowed the applicant to eventually submit a properly executed oath or declaration, a requirement under 35 § 371(c)(4), because the applicant's international application was not filed and the national fee was not paid prior to commencement of the national stage. The PTO may notify the applicant of a missing oath or declaration "[i]f [the] applicant

Patent. As noted above, this patent was asserted against Exela in a patent infringement suit filed on August 18, 2011.

III. Argument and Basis for Exela's Petition

The PTO had no authority under the Patent Statute or under the U.S. Constitution to revive abandoned US application no. 10/332,060 under the circumstances described herein. Indeed, the PTO's actions violated at least the express provisions of 35 U.S.C. § 371(d), and Article I, Section 8, Clause 8 of the U.S. Constitution. Accordingly, the PTO should reconsider and withdraw its petition decision of April 23, 2003, attached hereto as Exhibit B. Exela's arguments are presented in more detail below.

A. The PTO Violated 35 U.S.C. § 371(c)-(d) When It Revived Application No. 10/332,060 Under the "Unintentional" Standard

There is no question that the applicants for the '218 patent did not comply with the statutory requirements for filing a U.S. national stage application under 35 U.S.C. § 371 during prosecution of the '218 patent. As such, the application that led to issuance of the '218 patent automatically went abandoned pursuant to 35 U.S.C. § 371(d). The Patent Statute is crystal clear on this point. *See* 35 U.S.C. § 371(d) ("Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable."). The express statutory language requires that, once abandoned, a national stage application can only be revived under the more stringent "unavoidable standard." In this regard, see *Aristocrat Techs. v. Int'l Game Tech.*, 491 F. Supp.2d 916 (N.D. Cal. 2007).

complies with paragraph (b) of this section before expiration of thirty months from the priority date" 37 C.F.R. 1.495(c)(1). Here, the PTO notified the applicant of the missing oath or declaration and allowed the applicant to submit the missing document well after commencement of the national stage even though the requirements of 37 C.F.R. 1.495(b) were not met. The PTO's contravention of 35 U.S.C. § 371 and the applicable regulations also violates at least § 706(2) of the APA.

In *Aristocrat*, the district court held that the PTO lacked authority to revive an application abandoned under 35 U.S.C. 371, unless the applicant's delay was "unavoidable" rather than "unintentional." The court reasoned that 35 U.S.C. 41(a)(7), which expressly allows for a revival of applications after an "unintentional" delay, "does not modify or alter ... Section 371, which expressly require [sic] 'unavoidable' delays in order to revive abandoned applications." As noted, the plain language of Section 371(d) is clear and unambiguous on this point. It explicitly states that a patent application "shall be regarded" as abandoned unless it can be shown that the delay in meeting the national stage requirements was "unavoidable." This section of the Patent Statute does not even reference, let alone authorize, revival of a national stage application under an "unintentional" standard. As the PTO is well-aware, a standard principle of statutory construction is *expressio unius est exclusion alterius*, meaning that the mention of one thing implies exclusion of another thing. See *National R.R. Passenger Corp. v. National Ass'n of R.R. Passengers*, 414 U.S. 453, 458 (1974); see also *Botany Worsted Mills v. United States*, 278 U.S. 282, 289 (1929) ("[W]hen a statute limits a thing to be done in a particular mode, it includes the negative of any other mode.").

As the patent statute 35 U.S.C. § 371(d) specifically states that the "unavoidable" standard must be satisfied to revive an abandoned national stage application, the statute implicitly excludes revival of such applications under the lesser "unintentional" standard. Furthermore, courts have consistently adhered to the distinction between "unavoidable" and "unintentional" standards. In this context, "unavoidable" conduct is tantamount to the most unforeseen of circumstances causing an application to go abandoned. For example, where an applicant takes all reasonable steps to avoid the abandonment and, through no fault of its own, the application still goes abandoned, "unavoidable" delay may be found. See, e.g., *Futures Tech., Ltd. v. Quigg*, 684 F. Supp. 430 (E.D. Va. 1988) (finding "unavoidable" standard met where third-party fraud or misrepresentation caused the

application to go abandoned.). However, the case law is clear that mere “unintentional” delay does not meet the stringent “unavoidable” delay standard. *See Smith v. Mossinghoff*, 671 F.2d 533 (D.C.Cir.1982) (holding that where applicant’s attorney missed deadline because he was preoccupied with other legal matters and was in the process of moving his residence, applicant did not establish unavoidable delay); *Rydeen v. Quigg*, 748 F.Supp. 900 (D.D.C.1990) (holding that failure to pay maintenance fee because patentee’s attorney had not received customary notice from PTO alerting him it was due was not sufficient to establish unavoidable delay because PTO has no duty to provide notice that maintenance fee is due). Federal courts have clearly recognized that under Title 35 the “unavoidable” standard is distinct from the “unintentional” standard. The PTO’s own MPEP is consistent on this point. *See* MPEP § 711.03(c) (“That is, ‘unavoidable’ delay and ‘unintentional’ delay are not alternatives.”).

Requiring that applicants meet the more stringent “unavoidable” standard strikes a balance between the competing interests of protecting the rights of inventors whose applications become abandoned through no fault of their own, and the “stringent requirements for patent protection [which] seek to assure that ideas in the public domain remain there for the free use of the public.” *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Indeed, “an inventor may abandon his invention, and surrender or dedicate it to the public. This inchoate right, thus once gone, cannot afterwards be resumed at his pleasure; for, where gifts are once made to the public in this way, they become absolute. Thus, if a man dedicates a way, or other easement to the public, it is supposed to carry with it a permanent right of user.” *Pennock*, 27 U.S. at 16. To meet the constitutional mandate of ensuring that patents do not remove ideas that are already in the public domain, Congress has chosen the most stringent of standards for reviving abandoned national stage applications. The PTO has no authority to strike a different balance or to rewrite the Patent Act to allow for a lesser

standard for reviving abandoned national stage patent applications. 35 U.S.C. § 2(b); *Koninklijke Phillips Elec. NV v. Cardiac Science*, 590 F.3d 1326, 1336 (Fed. Cir. 2010) (“The PTO lacks substantive rulemaking authority.”).

Accordingly, the PTO must reconsider and ultimately withdraw its March 2003 decision to revive the application that led to issuance of the ‘218 patent. The PTO’s actions in reviving this application are contrary to the express language of § 371(d) of the Patent Act and must be corrected for this reason standing alone.⁵

B. The PTO’s Revival of the ‘218 Patent Application Violated Article I, Section 8, Clause 8 of the Constitution

Besides violating the express mandate of 35 U.S.C. § 371(d), the PTO’s revival of the application that led to issuance of the ‘218 patent also violated the United States Constitution. Specifically, Congress’ authority for the Patent Act is derived from Article I, Section 8, Clause 8 of the U.S. Constitution, which empowers Congress to pass laws that “promote the Progress of Science and useful Arts” In this regard, the Supreme Court has declared that,

Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must “promote the Progress of . . . useful Arts.” *This is the standard expressed in the Constitution and it may not be ignored.*

Graham v. John Deere, 383 U.S. 1, 5-6 (1966) (emphasis added).

⁵ The PTO again failed to follow its own regulations when it allowed the applicant to claim foreign priority. According to 37 C.F.R. § 1.55(a)(1)(ii), an applicant that enters the national stage from an international application is only entitled to foreign priority “after compliance with 35 U.S.C. 371.” 37 C.F.R. § 1.55(a)(1)(ii). As explained above, the applicant never complied with 35 U.S.C. § 371. The PTO’s contravention of the applicable regulations also violates at least § 706(2) of the APA.

With these constitutional constraints on Congress' patent powers in mind, Congress has declared that an application abandoned under 35 U.S.C. §371 can only be revived if the abandonment was "unavoidable." See 35 U.S.C. § 371(d). As noted above, use of this more stringent standard makes sense considering that the Constitution does not "authorize the issuance of patents whose affects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (quoting *Graham v. John Deere*). By use of the "unavoidable" standard, Congress has ensured that the applicant has taken all reasonable steps to prevent the application from becoming abandoned, and thus has complied with the constitutional command that the patent rights, "once gone, cannot afterwards be resumed at [the inventor's] pleasure; for, where gifts are once made to the public in this way, they become absolute." *Pennock*, 27 U.S. at 16.

By allowing the application to be revived under the lesser "unintentional" standard, the PTO has allowed the applicant to remove public information "at his pleasure," which is contrary to the constitutional command of promoting the progress of science and the useful arts. Indeed, through enactment of 35 U.S.C. § 371(d), Congress has, subject to the constitutional restraints, laid down the law that removal of an invention from the public domain requires a showing that is way more stringent than the mere filing of a form, which receives no PTO scrutiny, and a small fee. The Constitution demands nothing less. *Graham*, 383 U.S. at 6 ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available ... This is the standard expressed in the Constitution and it may not be ignored."). Thus, PTO's revival of the application that led to issuance of the '218 patent clearly violates the U.S. Constitution.

Moreover, the Supreme Court has held that the same Constitutional restraints that apply to Congress apply equally to the PTO: "It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to *give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of Congress.*" *Id.* at 6 (emphasis added). By departing from Congress' statutory scheme for revival of national stage patent applications under 35 U.S.C. § 371(d), the PTO has not only exceeded its limited statutory authority,⁶ but has also violated the Constitution. For this reason alone, the PTO should reconsider and withdraw its March 2003 decision to revive the application that led to issuance of the '218 patent. Such action is mandated by the Constitution.

IV. Conclusion

Based upon the above, Exela petitions the Director to reconsider and ultimately withdraw its grant of the petition to revive filed during prosecution of the '218 patent. The instant petition should be considered by the PTO because it addresses a situation "not specifically provided for in the regulations" and because the PTO has the inherent authority to reconsider its prior decisions. *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008) ("Courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions."); *Macktal v. Chao*, 286 F.3d 822, 825-26 (5th Cir. 2002) ("[I]t is generally accepted that in the absence of aspecific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.").


Accordingly, it is respectfully requested that the PTO's Office of Petitions: (i) suspend any rules standing in the way of its consideration of the Exela Petition; and (ii) reconsider and ultimately

⁶ The PTO has no substantive rule making authority, and has no power to apply the Patent Act in a manner that contradicts Congress' chosen statutory scheme. *Koninklijke Phillips*, 590 F.3d at 1336.

withdraw its April 25, 2003 decision granting SCR Pharmatop's Petition to revive application no. 10/332,060 that led to issuance of the '218 patent. Based upon the clear and unambiguous statutory language of 35 U.S.C. § 371(d) and the constitutional mandate to promote the progress of science and useful arts, the PTO should never have granted SCR Pharmatop's petition to revive nor should the PTO have issued the '218 patent.

Date: November 29, 2011

Respectfully submitted,

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Attachments: Exhibit A (18 pages)
Exhibit B (3 pages)